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| 09/914,544 | 03/19/2002 | Laurent Di Costanzo | C1190/20009 | 7903 |

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| EXAMINER | |
|---|---|
| DICKINSON, PAUL W | |
| ART UNIT | PAPER NUMBER |
| 1618 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 12/19/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/914,544 | COSTANZO ET AL. | |
| | Examiner | Art Unit | |
| | PAUL DICKINSON | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10/13/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's arguments, filed 10/13/2008, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *Response to Arguments*

### *Claim Rejections - 35 USC § 112, Second Paragraph*

The rejection of Claim 41 under 35 U.S.C. 112, second paragraph, is maintained.

Applicant argues that independent claim 21 now clarifies that "the rest of the lubricating agent, if any, is comprised in the dry mixture". This clarification allows the embodiment wherein "all of the lubricating agent of the tablet is distributed on the outer surface of the tablet" as recited in dependent claim 41.

Applicant's arguments have been fully considered but are not found persuasive. Independent claim 21 recites "said tablet comprising a dry mixture of an active substance and excipients including a disintegrating agent, and a soluble agent with binding properties, and a lubricating agent in powder form, wherein more than half of the lubricating agent is distributed on the tablet surface and the rest of the lubricating agent, if any, is comprised in the dry mixture". Independent claim 21 states that the lubricating agent is a required component of the dry mixture by reciting "a dry mixture of an active substance... and a lubricating agent" and then states that the lubricating agent

is only an optional component of dry mixture by reciting "and the rest of the lubricating agent, if any, is comprised in the dry mixture" (see ***New Grounds of Rejection: Claim Rejections - 35 USC § 112, Second Paragraph*** below). Therefore, independent claim 21 is now self-inconsistent, and it is unclear how the embodiment disclosed in dependent claim 41, namely, that all of the lubricating agent of the tablet is distributed on the outer surface of the tablet, is possible.

***Claim Rejections - 35 USC § 102***

The rejection of Claims 21-25, 29-30, 33, 35 and 41 under 35 U.S.C. 102(b) as being anticipated by US 5725880 ('880) is maintained.

Applicant argues that '880 does not teach or even suggest a tablet comprising an active substance wherein the active substance is coated, let alone a tablet comprising an active substance, wherein the active substances is in the form of coated microcrystals or coated microgranules. The step of wet granulation disclosed by '880 does not result in the active substance being coated (i.e. being covered with a layer of substance spread over its outer surface). Furthermore, '880 teaches that the medicinal active ingredient can be selectively delivered to any specific site in the intestinal tract and accordingly, the pharmaceutical preparation does not dissolve in the mouth on contact with saliva in less than 30 seconds. Applicant further argues that '880 does not teach or even suggest a tablet comprising a lubricating agent distributed on the tablet surface, let alone a tablet comprising a lubricating agent, wherein more than half of the lubricating agent is distributed on the tablet surface.

Applicant's arguments have been fully considered but are not found persuasive. In the method disclosed in Example 3 of '880, the 5-Aminosalicylic acid and corn starch are wet granulated with a binding solution of polyvinylpyrrolidone. Applicant argues that in the resulting granules, the active substance may be considered as trapped, dispersed, or embedded within a mixture of corn starch and polyvinylpyrrolidoine, but the active substance is not coated. The Examiner is interpreting the term "coated nanocrystals or coated microgranules" recited in instant claim 21 to not be limited to discrete particles consisting of the active ingredient uniformly coated with a single substance. If Applicant believes that this structure is what distinguishes the present invention from the prior art, this structure should be recited in the claims. As presently claimed, the Examiner does not see the distinction between granules of an active substance being embedded in corn starch and polyvinylpyrrolidone, and granules of an active substance being coated with corn starch and polyvinylpyrrolidone. In either case, a layer of corn starch and polyvinylpyrrolidone are at least partly, if not entirely, enveloping the active substance granules. Regarding Applicant's argument that the wet granulation would result in a homoegenous mixture of the active substance, corn starch and polyvinylpyrrolidone, the method is clear that polyvinylpyrrolidione acts as a binder, and it is reasonable that it binds the active substance granules with the corn starch granules. This satisfies instant claim 21 which requires that "the active substance is in a form of coated microcrystals or coated microgranules."

Regarding the recitation in Claim 21 that the directly compressible tablet is "adapted to disintegrate in the mouth on contact with saliva in less than 30 seconds", it

has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.* The Examiner notes that the required contents of the dry mixture and tablet surface are unclear (see ***New Grounds of Rejection: Claim Rejections - 35 USC § 112, Second Paragraph*** below).

***Claim Rejections - 35 USC § 103***

The rejection of Claims 21-41 under 35 U.S.C. 103(a) as being unpatentable over Hunter et al (US 6391337) in view of Schmitz et al (US 6079968) in further view of Valentine et al (US 4684534) is maintained. The rejection of Claims 31 and 42-47 under 35 U.S.C. 103(a) as being unpatentable over Hunter et al (US 6391337) in view of Schmitz et al (US 6079968) is maintained.

Applicant's arguments center around Hunter et al, and specifically, whether or not coated microgranules of acetaminophen are taught by Hunter et al. Applicant argues that in certain embodiments the direct compression vehicle includes a microcrystalline cellulose which has been coprocessed with silicon dioxide, wherein the microcrystalline cellulose may reasonably be considered to be coated with silicon dioxide. Applicant argues that in embodiments where silicon dioxide is a part of the pharmaceutical dosage form, silicon dioxide is high-shear mixed with acetaminophen. The high-shear mixing is different from the protocol used to obtain microcrystalline cellulose coprocessed with silicon dioxide. Hunter et al does not teach or suggest that

high-shear mixing results in coating or partial coating of acetaminophen granules with silicon dioxide.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner agrees that when silicon dioxide is used in the formulation, silicon dioxide is high-shear mixed with acetaminophen. Hunter et al clearly teaches that the acetaminophen particle size is chosen so that the particles remain in tact under high shear mixing conditions (see col 7, lines 55-67). Therefore, it is reasonable that when the acetaminophen particles are high shear mixed with silicon dioxide, the result is not particles comprising a homogenous mixture of acetoaminophen and silicon dioxide, but rather, discrete acetaminophen particles coated with silicone dioxide. For the sake of argument, even if the high shear mixing of acetoaminophen and silicon dioxide were to result in particles comprised of a homogenous mixture of acetaminophen and silicon dioxide, a lubricant is subsequently added to the granules under less vigorous conditions and would coat the acetaminophen/silicon dioxide particles (see col 10, lines 1-23; col 13, line 54 to col 14, line 4). The Examiner interprets the reference to indicate that the acetaminophen particles remain intact, and are coated with silicon dioxide during the high sheer mixing process, and if the second mixing step is performed with the lubricant as taught by the reference, the acetoaminoiphen particles would also be coated with the lubricant.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 21 recites “said tablet comprising a dry mixture of an active substance and excipients including a disintegrating agent, and a soluble agent with binding properties, and a lubricating agent in powder form, wherein more than half of the lubricating agent is distributed on the tablet surface and the rest of the lubricating agent, if any, is comprised in the dry mixture”. Independent claim 21 states that the lubricating agent is a required component of the dry mixture by reciting "a dry mixture of an active substance... and a lubricating agent" and then states that the lubricating agent is only an optional component of dry mixture by reciting “and the rest of the lubricating agent, if any, is comprised in the dry mixture"

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

December 12, 2008